

IN THE UNITED STATES DISTRICT COURT FOR  
THE EASTERN DISTRICT OF VIRGINIA  
Alexandria, Virginia

**Raymond A. Evans,**

**Plaintiff,**

V.

Civil Action No. 1:04cv1218

**Mentor Corporation,**

**Defendant.**

## MEMORANDUM OPINION

This matter came before the court for hearing on defendant's motion for summary judgment (No. 20) on June 15, 2005. Defendant's motion has been fully briefed and argued. For the following reasons, the court finds that there are no genuine issues of material fact for trial, and that defendant is entitled to summary judgment.

Plaintiff claims defendant negligently designed, manufactured, distributed, assembled, and/or sold a prosthesis and negligently failed to properly inspect and test the prosthesis before it was provided to Dr. Antonio Michell for implantation in plaintiff's body. Plaintiff also asserts claims for failure to warn, implied warranty of merchantability, and defective design and manufacture. In his opposition to defendant's motion for summary judgment, plaintiff stated that he would present no evidence with regard to design defects.

## Undisputed Facts

The following facts are undisputed. Dr. Antonio Michell, the surgeon who performed the

procedure on plaintiff, testified that prior to implantation of the prosthesis into plaintiff, the cylinders were filled with saline to test for leaks. Michell Dep. Trans. at 34:18-36:15. Nothing was found that indicated any problem with the cylinders of the prosthesis. *Id.* at 36:15.

Dr. Michell admitted that contact with a sharp instrument could cause a leak in the prosthesis. *Id.* at 84:12-13.

Plaintiff has no tangible evidence or testamentary evidence that a leak or other defect existed at the time the prosthesis left defendant's hands.

Plaintiff admits he was warned of and appreciated the risk that the device could fail. Evans Dep. Trans. at 31:2-23; 32:1-11. Plaintiff understood prior to implantation that infection was a risk of surgery. *Id.* at 30:2-22. Defendant relies on the physician to warn the patient of all risks involving implantation and use of its prosthesis. *See* exhibit L to defendant's brief in support of motion for summary judgment (No. 21). Defendant provides its physicians with comprehensive documentation regarding the risks and benefits of its medical devices. *Id.*

### **Legal Standards**

Plaintiff has the burden of showing that any alleged product defect was the cause of his injuries. *McCauley v. Purdue Pharma L.P.*, 331 F. Supp. 2d 449 (W.D. Va. 2004). To succeed on a product liability claim under Virginia law, which applies in this diversity action, plaintiff must demonstrate that a product defect is the only reasonable explanation or cause of the complained-of injury. *Hartwell v. Danek Med., Inc.*, 47 F. Supp. 2d 703, 707 (W.D. Va. 1999). Further, "proof of legal causation in a medical device case must be by expert testimony and the expert's opinion must be stated in terms of reasonable probability." *Id.* at 707 (citing *Rohrbough v. Wyeth Laboratories, Inc.*, 916 F.2d 970, 972 (4th Cir. 1990)).

A party is entitled to summary judgment if the “pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). On a motion for summary judgment, the court must first consider whether there are any issues of material fact. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In making this determination, the court must assess the factual evidence and all inferences must be drawn in the light most favorable to the non-moving party. *See Anderson*, 477 U.S. at 255.

Summary judgment is appropriate when a party who will bear the burden at trial fails to make a showing sufficient to establish an essential element of the case. *Laughlin v. Metropolitan Wash. Airports Auth.*, 149 F.3d 253, 258 (4th Cir. 1998). In order to defeat a summary judgment motion, “the nonmoving party must come forward with ‘specific facts showing that there is a genuine issue for trial.’” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (U.S. 1986)(quoting Fed. R. Civ. P. 56(e)). The moving party on a summary judgment motion can prevail by showing that there is an absence of evidence by which the non-movant can prove his case. *Cray Communications v. Novatel Computer Sys.*, 33 F.3d 390, 393-394 (4th Cir. 1994) (citations omitted).

### **Analysis**

Defendant is entitled to summary judgment because plaintiff cannot establish causation or existence of a product defect; and plaintiff cannot defeat the learned intermediary doctrine.

### **I. No evidence of causation or product defect**

Plaintiff's only expert is his treating physician, Dr. Michell, who cannot identify the cause of the only defect alleged in plaintiff's complaint. In his deposition, Dr. Michell testified that he does not know how the pinhole leak got in the cylinders of the prosthesis. Indeed, Dr. Michell can only speculate as to the cause of the leak in the prosthesis, and speculative testimony cannot adequately support plaintiff's theory of causation. *See Rohrbough v. Wyeth Laboratories, Inc.*, *supra*. Therefore, Dr. Michell's testimony does not create a genuine issue of material fact.

At oral argument, plaintiff cited *Southern States Cooperative, Inc. v. Doggett*, 292 S.E.2d 331 (Va. 1982) in support of the proposition that causation in a products liability suit can be established by circumstantial evidence. *Doggett* holds that "[p]roof of facts from which it can be reasonably inferred that an act or circumstance sought to be established occurred or existed is sufficient to authorize submission of the issue to the jury. But such circumstantial evidence must be sufficient to establish that the result alleged is a probability rather than a mere possibility." *Id.* at 335 (quoting *Richardson v. Lovvorn*, 101 S.E.2d 511, 514 (1958)). Plaintiff has not produced evidence that could support such a finding by a jury.

Plaintiff contends that the prosthesis was damaged at the time it left defendant's hands but did not develop a leak until after implantation into plaintiff's body. In support of this theory, plaintiff offers Dr. Michell's opinion that Dr. Michell did not do anything to create the pinhole leak in the cylinder. Michell Dep. Trans. at 69:9-20. Plaintiff also points out that defendant's representative, Mark Bartenfelder, concedes that a damaged cylinder may not leak immediately after it was damaged. Bartenfelder Dep. Trans. at 43:23-44:11. This circumstantial evidence that a product defect may have caused the leak is speculative at best and cannot establish that

plaintiff's injuries were probably caused by a product defect. Speculative evidence that does not meet the standard of reasonable probability is not sufficient to create a jury issue. *Southern States Cooperative, Inc. v. Doggett, supra*.

Plaintiff's speculative evidence is countered by un rebutted expert testimony that meets the standard of reasonable medical probability. Defendant offered evidence that surgical error was the likely cause of plaintiff's injuries. Defendant's expert Dr. Klousia stated in his expert report that "it is my expert opinion that, within a reasonable degree of professional certainty" surgical error caused the leak in the prosthesis. Report of John W. Klousia, exhibit J to defendant's brief in support of motion for summary judgment (No. 21).

Dr. Klousia also stated that "[i]f there had been a defect created during the manufacture or packaging process, there is an overwhelming likelihood that this would have been discovered when the device was inflated/tested in the operating room prior to insertion." *Id.* Furthermore, Dr. Michell admitted it would be unusual if the prosthesis was the cause of plaintiff's infection. Michell Dep. Trans. at 60:2-61:21.

In sum, plaintiff's theory that a product defect caused his injuries is based on speculation and conjecture unsupported by evidence in the record.

Because plaintiff cannot establish defendant's product was defective or caused any injury, plaintiff's claims for negligence, manufacturing defect, and breach of warranty necessarily fail.

## **II. Plaintiff cannot defeat the learned intermediary doctrine.**

Plaintiff's failure to warn claim is barred by the learned intermediary doctrine. That doctrine provides that "manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product." *Talley v.*

*Danek Med.*, 7 F. Supp. 2d 725, 730 (E.D. Va. 1998), *aff'd* at 179 F.3d 154 (4th Cir. 1999). *See also Pfizer, Inc. v. Jones*, 272 S.E.2d 43 (Va. 1980). The doctrine applies in “circumstances where (1) ethical drugs or medical devices that can be prescribed or installed only by a physician are involved and (2) a physician prescribes the drug or installs the medical device after having evaluated the patient.” *Talley v. Danek Med.*, 179 F.3d 154, 163 (4th Cir. 1999). The prosthesis is a medical device that can be installed only by a physician; and Dr. Michell, acting as plaintiff’s physician, installed the prosthesis after having evaluated plaintiff. Under the learned intermediary doctrine, defendant satisfied its duties by providing detailed product information to Dr. Michell.

### **Conclusion**

For the reasons stated above, the court finds that the evidence in the record establishes that defendant is entitled to summary judgment as a matter of law.

An appropriate order accompanies this opinion.

/s/

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Thomas Rawles Jones, Jr.  
United States Magistrate Judge

Alexandria, Virginia  
June 28, 2005